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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/359,975	07/23/99	WEINER	UPAP-0345

HM12/0215

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EXAMINER	
SANDALS,W	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 02/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/359,975	Weiner et al.
Examiner	**Group Art Unit**
WILLIAM SANDALS	1636

☒ Responsive to communication(s) filed on *Jul 23, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *58-121* is/are pending in the application.

Of the above, claim(s) *60, 61, 65, 66, 73, 77-83, 87-93, and 97-114* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-121* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 58, 59, 67-72 and 115-121, drawn to a pharmaceutical composition comprising DNA and a function enhancer and a method of use, classified in class 424, subclass 184.1.

II. Claim 60, drawn to a T cell receptor antigen, classified in class 424, subclass 184.1.

III. Claims 61, 73, 77-83 and 87-93, drawn to a pathogen antigen, classified in class 424, subclass 184.1.

IV. Claims 62-64, 74-76, 84-86 and 94-96, drawn to an intracellular pathogen antigen, classified in class 424, subclass 184.1.

V. Claims 65, 66 and 97-105, drawn to a hyperproliferative disease antigen, classified in class 424, subclass 184.1.

VI. Claim 106, drawn to a melanoma antigen, classified in class 424, subclass 184.1.

VII. Claim 107, drawn to a lymphoma antigen, classified in class 424, subclass 184.1.

VIII. Claims 108-114, drawn to an autoimmune antigen, classified in class 424, subclass 184.1.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II-VIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of the pharmaceutical composition comprising DNA is generic to the specific and separately patentable invention of a DNA encoding a T cell receptor antigen. The subcombination has separate utility such as the combination can be used with multiple DNA encoded antigens, such as those enumerated in Groups II-VIII. Group I is generic to Groups II-VIII and will be examined with any one of the elected Groups II-VIII.

3. Inventions of Groups II-VIII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions of Groups II-VIII each has separate utility such as immunizing a subject against a specific antigen. See MPEP § 806.05(d).

4. Because these inventions are distinct for the reasons given above and the search required for each of Groups II-VIII is not required for any and each of the other remaining Groups III-VIII, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Mark DeLucca, Esq. on January 11, 2000 a provisional election was made with traverse to prosecute the invention of Groups I and IV, claims 58, 59, 62-64, 67-72, 74-76, 84-96 and 115-121. Affirmation of this election must be made by applicant in replying to this Office action. Claims 60, 61, 65, 66, 73, 77-83, 87-93 and 97-114 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

8. Subsequent to the petition to change inventorship under Rule 148(b) and payment of the fee on July 23, 1999, the Oath/Declaration has been amended to delete inventors Leslie R. Coney, Michael J. Merva and Vincent R. Zurawski, Jr.

Drawings

9. The drawings as submitted on July 23, 1999, have been approved by the draftsman.

Specification

10. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

11. Claims 62, 74, 84 and 94 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend from claims withdrawn from examination by restriction.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96 and 115-121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleotide

function enhancer bupivacaine, does not reasonably provide enablement for all compounds of the claimed structures. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claim is drawn to a pharmaceutical composition comprising a nucleotide function enhancer and a DNA and a method of use. While applicants have shown that bupivacaine is a nucleotide function enhancer, they have not demonstrated that any of the other claimed compounds will act as nucleotide function enhancers. In order to do so, undue experimentation is required. Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors. Many of these factors have been summarized in *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

The Wands factors as they apply to the instant claimed invention are as follows:

a- The quantity of experimentation necessary to reduce the instant claimed invention to practice would involve using each of the claimed compounds in the method and determining if it has any activity as a nucleotide function enhancer.

b- The prior art is silent as to the ability of the claimed compounds to act as nucleotide function enhancers. As such, there is no certain knowledge other than conjecture to support the claimed activity of said claimed compounds.

c- Since there is no certain knowledge of the activity of these compounds, this amounts to a trial and error method of discovery, and is not enabled by the claims or specification.

d- Therefore, given the analysis above, it must be considered that the skilled artisan would have needed to have practiced considerable non-routine, trial and error experimentation to enable the full scope of the claims.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 58 (and all dependent claims) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 58 recites the limitation "polynucleotide function enhancer" in line 5. There is insufficient antecedent basis for this limitation in the claim. It is assumed for the purposes of examination that due to an oversight, the word "enhancer" was omitted from line 2, which would otherwise read "polynucleotide function enhancer", satisfying the antecedent basis.

Conclusion

17. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If

applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist, whose telephone number is (703) 308-0196.

William Sandals, Ph.D.

Examiner

February 11, 2000

George C. Elliott, Ph.D.
Supervisory Patent Examiner
Technology Center 1600